## REMARKS

This reply is intended to be completely responsive to the Final Office Action dated August 19, 2009.

### Status

Claims 19-23 and 42-76 are pending in this application.

Claims 19-23 and 42-76 are rejected.

Upon entry of this amendment, claim 19 will be amended, and new claims 77 and 78 will be added to provide additional claims of varying scope.

Applicant believes that each of the rejections raised by the Examiner have been addressed and the application is in condition for allowance. Reconsideration and allowance of the application, as amended, is respectfully requested.

### Claim Rejections – 35 U.S.C. § 103

On pages 2-5 of the Office Action, the Examiner rejected claims 19-23 and 42-76 under 35 U.S.C. §103(a) as being unpatentable over Muhlhausler et al., U.S. Patent No. 6,524,342, in view of Dwyer et al., U.S. Patent No. 7,122,056. For the reasons stated below, Applicant respectfully asserts that claims 19-23 and 42-76 are patentable over Muhlhausler et al. in view of Dwyer et al. under 35 U.S.C. §103(a).

I. Method Claims 19-23 and 76

For the reasons set forth below, Applicant respectfully asserts that independent method claim 19, and dependent claims 20-23 and 76, are not obvious over Muhlhausler et al. in view of Dwyer et al. because the combination of Muhlhausler et al. and Dwyer et al. fails to disclose, teach or suggest at least one element of independent method claim 19.

A. Independent Method Claim 19

Independent claim 19 has been amended to further distinguish the claimed method from the teachings of Muhlhausler et al. and Dwyer et al. Independent claim 19, as amended, recites a "method of replacing a shaft of a joint prosthesis having a body, a head, and a shaft after the joint prosthesis has been implanted in a patient" including, among other steps, the step of "removing the shaft from the patient without removing both the body and the head from the patient and without decoupling the head from the body" and the step of "coupling the replacement shaft to the body without removing both the body and the head from the patient and without decoupling the head from the body." As set forth in Applicant's specification, the method, such as recited in claim 19, provides for replacement of the shaft of a joint prosthesis without requiring removal of the entire artificial joint. See e.g., paragraph [0006]. Specifically, in one particular application of such a method, Applicant's specification identifies the desirability of replacement of the original shaft with a longer shaft to mend an injury that occurs distal to the original shaft, such as a fracture or metastatic lesion, without requiring removal of other components of the artificial joint. See e.g., paragraphs [0036] and [0039].

Applicant respectfully asserts that neither Muhlhausler et al. nor Dwyer et al. disclose, teach or suggest the step of "removing the shaft from the patient without removing both the body and the head from the patient and without decoupling the head from the body" or the step of "coupling the replacement shaft to the body without removing both the body and the head from the patient and without decoupling the head from the body," as recited in independent claim 19. Further, Applicant respectfully asserts that neither Muhlhausler et al. nor Dwyer et al. are directed toward or even recognize the desirability of replacement of the shaft of a joint prosthesis without requiring removal or revision of the other components of the artificial joint.

In contrast to claim 19, Muhlhausler et al. discloses a "shoulder endoprosthesis" including "a shaft 10," "a middle section 30 fitted onto it [shaft 10]," and "a holder 32 [that] serves to secure a head 40." Col. 3, line 66 to col. 4, line 1 and col. 4, line 5. According to Muhlhausler et al. the "objective of the invention is a modularly constructed shoulder prosthesis

which suits very differing anatomical conditions." Col. 2, lines 42-44. Muhlhausler et al. addresses this problem by teaching a shoulder prosthesis that includes a middle section that is adjustable along the length of the prosthesis shaft and adjustable in its rotational position about the axis of the prosthesis shaft. See col. 2, lines 48-50. In other words, while Muhlhausler et al. teaches an adjustable joint prosthesis that allows for adjustment of shaft length and rotational positioning, Muhlhausler et al. does not teach either the step of "removing the shaft from the patient without removing both the body and the head from the patient and without decoupling the head from the body" or the step of "coupling the replacement shaft to the body without removing both the body and the head from the patient and without decoupling the head from the body," as recited in independent claim 19.

Dwyer et al. does not remedy the deficiencies of Muhlhausler et al. In contrast to claim 19, Dwyer et al. discloses a "modular prosthesis 100" having a "sleeve component 14," a "stem component 18," and a "neck component 12" having a "trunnion 26" at one end that joins "neck component 12" to "head component 16." See col. 15, lines 63-67, col. 5, lines 48-50, col. 6, lines 31-33, and Figs. 1 and 5. According to Dwyer et al., objects of the invention include providing "enhanced locking characteristics," providing a "prosthesis that is 'self-locked' by the functional loads generated during use," and providing a "prosthesis that provides a high degree of flexibility" in positioning of the head component. See col. 4, lines 20-30. While Dwyer et al. does teach that removal and replacement of the stem of the prosthesis is sometimes needed, Dwyer et al. only teaches such removal of the stem "along with the other components which have already been removed." See col. 10, lines 39-42 and FIG. 4. Thus, Dwyer et al. does not teach either the step of "removing the shaft from the patient without removing both the body and the head from the patient and without decoupling the head from the body" or the step of "coupling the replacement shaft to the body without removing both the body and the head from the patient and without decoupling the head from the body," as recited in independent claim 19.

Further, neither Muhlhausler et al. nor Dwyer et al. provide any teaching regarding the desirability of replacement of the shaft of a prosthesis without requiring removal of the other

components of the prosthesis as identified in Applicant's specification. Thus, Applicant respectfully asserts that even if, as argued by the Examiner, the combination of Muhlhausler et al. and Dwyer et al. teaches the *structure* of the prosthesis as taught by Applicant's specification (a point Applicant does not agree with), the combination of Muhlhausler et al. and Dwyer et al. does not teach the *method* as taught by Applicant and as claimed in independent claim 19.

Accordingly, because the combination of Muhlhausler et al. and Dwyer et al. fail to disclose, teach or suggest at least one element or limitation of independent method claim 19, Applicant respectfully asserts that independent claim 19, and dependent claims 20-23 and 76, are patentable over Muhlhausler et al. in view of Dwyer et al. under 35 U.S.C. § 103(a).

B. Dependent Method Claim 23

In addition to the reasons set forth regarding independent claim 19, Applicant respectfully asserts that dependent claim 23 is further patentable over Muhlhausler et al. and Dwyer et al.

Dependent claim 23 recites "wherein the replacement shaft is longer than the shaft." Neither Muhlhausler et al. nor Dwyer et al. teach replacement of the shaft of a prosthesis with a longer shaft as recited in dependent claim 23.

As noted above, Dwyer et al. generally teaches that removal and replacement of the shaft of the prosthesis may be necessary "in certain cases." See e.g., col. 10, lines 39-42. Muhlhausler et al. teaches adjustment of shaft length. See e.g., col. 4, lines 21-24. Further, Muhlhausler et al. and Dwyer et al. both generally teach providing prosthesis components with differing lengths and sizes to fit a particular patient. See e.g., col. 3, lines 34-38 of Muhlhausler et al., and col. 2, lines 12-14 of Dwyer et al. However, neither Muhlhausler et al. nor Dwyer et al. teach replacement of the shaft of a prosthesis with a longer shaft as recited in dependent claim 23.

Accordingly, because the combination of Muhlhausler et al. and Dwyer et al. fail to disclose, teach or suggest at least one element or limitation of dependent method claim 23,

Applicant respectfully asserts that claim 23 is patentable over Muhlhausler et al. in view of Dwyer et al. under 35 U.S.C. § 103(a).

C. Dependent Method Claim 76

In addition to the reasons set forth above regarding independent claim 19, Applicant respectfully asserts that dependent claim 76 is further patentable over Muhlhausler et al. and Dwyer et al.

Dependent claim 76 recites "wherein the step of removing the shaft includes accessing the shaft via an end of the central canal nearest the head." Neither Muhlhausler et al. nor Dwyer et al. teach removing the shaft by accessing the shaft via an end of the central canal nearest the head as recited in dependent claim 76. As noted above, Muhlhausler et al. does not teach removal or replacement of a shaft. Dwyer et al. teaches removal of a shaft only after the other components of the joint prosthesis have been removed, and, as can be seen in FIG. 4, Dwyer et al. teaches removal of the shaft by directly accessing the shaft and not by "accessing the shaft via an end of the central canal nearest the head" as recited in claim 76. See col. 10, lines 39-42 and FIG. 4.

Accordingly, because the combination of Muhlhausler et al. and Dwyer et al. fail to disclose, teach or suggest at least one element or limitation of dependent method claim 76, Applicant respectfully asserts that claim 76 is patentable over Muhlhausler et al. in view of Dwyer et al. under 35 U.S.C. § 103(a).

II. Apparatus Claims 42-75

Independent claim 42 recites a "joint prosthesis system" including, among other elements, "a body having a first portion, a second portion, and a central canal, wherein the central canal extends through the second portion of the body" and "a head coupled to the first portion of the body, wherein the central canal extends through the second portion of the body at a position such that access is permitted to an end of the central canal nearest the head when the head is coupled

to the body." Independent claim 52, as amended, recites a "modular joint prosthesis … wherein the shaft may be removed from the patient after implantation of the prosthesis without also removing both the body and the articular surface from the patient and without decoupling the body from the articular surface." Independent claim 60, as amended, recites a "modular joint prosthesis system … wherein the second replacement shaft is used to replace the first shaft in the bone after implantation of the prosthesis into a patient without first removing both the body and the articular surface from the patient and without decoupling the articular surface from the body." Independent claim 75, as amended, recites an "artificial joint system … wherein the first shaft is removable from the central canal without removing both the body and the prosthetic head from the patient and without decoupling the prosthetic head from the body."

As discussed below, Applicant respectfully asserts that both Muhlhausler et al. and Dwyer et al. teach away from a combination, as suggested by the Examiner, that would result in the invention as recited in independent claims 42, 52, 60 and 75.

A. Muhlhausler et al. teaches away from modification of the shoulder prosthesis to function as a hip prosthesis.

Applicant understands the Examiner's argument to be that modification of the "shoulder endoprosthesis" of Muhlhausler et al. to function as a hip prosthesis, as taught by Dwyer et al., would require replacement of the oblong "head 40" of Muhlhausler et al. with the spherical "head component 16" of Dwyer et al., and with this modification, the shaft of Muhlhausler et al. would be removable without decoupling "head 40" from "middle section 30" of Muhlhausler et al.

However, Muhlhausler et al. teaches away from modifying its modular shoulder prosthesis to function as a hip prosthesis. Muhlhausler et al. distinguishes hip prostheses from shoulder prostheses by teaching that it is "relatively easy in the case of hip joints" to simply manufacture artificial joints "to suit every application possible." See col. 1, lines 39-46. According to Muhlhausler et al. "the hip joint is a ball-and-socket-joint and, consequently is

relatively easy to oversee in anatomical, biomechanical and kinematic terms." Col. 1, lines 44-46. In contrast to a hip prosthesis, Muhlhausler et al. teaches that "[c]onditions are … relatively complicated in the shoulder joint, as the shoulder joint guarantees an exceptionally large degree of movement and the cavity … covers only a small section of the capitulum." Col. 1, lines 52-55. Thus, Muhlhausler et al. teaches that it is the complexity of the shoulder joint that calls for the modular design of Muhlhausler et al. Accordingly, Applicant respectfully asserts that Muhlhausler et al. teaches away from the combination with Dwyer et al. to modify the "shoulder endoprosthesis" to function as a hip prosthesis, as suggested by the Examiner.

B. Dwyer et al. teaches away from prostheses including certain fasteners and neck components having through bores.

Muhlhausler et al. teaches a prosthesis that includes "a clamping element 20" and that by "screwing the threaded bolt 22 of the clamping element 20 into the threaded bore 12 in the proximal section of shaft 10, the shaft 10 is fixed to the middle section 30." Col 4, lines 11-16 and FIG. 2. Further, the "middle section 30" of Muhlhausler et al. includes a "through bore 34 with internal thread 35." Col. 4, lines 8-9. However, Dwyer et al. teaches the deficiencies of fasteners, such as "clamping element 20," and of neck components including through bores.

According to Dwyer et al. "a number of modular prostheses have heretofore been designed to include a distal stem component which has an upwardly extending post which is received into a bore defined in the distal neck component. A relatively long fastener, such as a screw or bolt, is utilized to secure the post within the bore." Col . 2, lines 28-33 (emphasis added). Dwyer et al. identifies a number of problems with such fasteners and neck component through bores.

According to Dwyer et al., "functional loading during use of the prosthesis may not provide a positive lock and may actually tend to urge the upwardly extending post of the distal stem component out of the bore defined in the proximal neck component. In such a case, the fastener (e.g. the screw or bolt) alone must absorb such loads. This creates a number of problems

since many of such functional loads tend to be axial in nature. In particular, by the nature of its design, axial loads exerted on a fastener such as a screw or bolt bear on the threads of the fastener thereby undesirably exerting a relatively large load to a relatively small surface area. Over time, such loads may degrade or even breach the mechanical integrity of the threads thereby potentially allowing the components to separate from one another." Col. 2, lines 35- 49 (emphasis added).

Further, according to Dwyer et al. "manufacture of such modular prosthesis is relatively difficult and, as a result, expensive. In particular, in order to utilize a long screw or bolt to secure the two components to one another, a relatively long bore must be drilled or otherwise machined through the entire length of the proximal neck component and at least a portion of the length of the distal stem component. Such drilling, often referred to as 'gun drilling', is relatively difficult to do since, amongst other things, it requires adherence to extremely strict tolerances thereby increasing costs associated with manufacture of the modular prosthesis." Col. 2, lines 50-60 (emphasis added).

Thus, Dwyer et al. teaches away from a prosthesis utilizing a "middle section 30" that includes a "through bore 34 with internal thread 35" and "a clamping element 20" as taught by Muhlhausler et al. Accordingly, Applicant respectfully asserts that Dwyer et al. teaches away from a combination with the "shoulder endoprosthesis" of Muhlhausler et al., as suggested by the Examiner.

C. Conclusion

Because both Muhlhausler et al. and Dwyer et al. teach away from the combination suggested by the Examiner, Applicant respectfully asserts that claims 42-75 are patentable over Muhlhausler et al. in view of Dwyer et al. under 35 U.S.C. § 103(a).

**New Claims**

Applicant has added new claims 77 and 78 to present additional claims of varying scope. New claims 77 and 78 depend from independent claim 19 and are patentable for at least the same reasons discussed above regarding claim 19.

In addition, Applicant respectfully asserts that new claims 77 and 78 are further patentable over Muhlhausler et al. and Dwyer et al. because Muhlhausler et al. and Dwyer et al. fail to disclose, teach or suggest a method wherein "the step of coupling the replacement shaft includes inserting the replacement shaft into the central canal via an end of the central canal nearest the head," as recited in claim 77, or a method "further comprising selecting a replacement shaft longer than the shaft such that the replacement shaft extends across a fracture in a bone of a patient, the fracture located distally from the distal end of the shaft," as recited in claim 78. Accordingly, Applicant respectfully requests allowance of new claims 77 and 78.

**Conclusion**

Claims 19-23 and 42-76 are pending in the present application. Upon entry of this amendment, claim 19 will be amended and new claims 77 and 78 will be added. Applicants believe that the present application is in condition for allowance. Favorable reconsideration of the application, as amended, is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

It should be noted that, for the sake of clarity and simplicity, Applicant's remarks have focused on the rejections of the independent claim and certain dependent claims set forth in the Office Action with the understanding that the dependent claims are patentable for at least the same reasons as the independent claims. Further, in addressing the Examiner's rejections, Applicant's remarks have set forth only some of the available arguments for patentability of the rejected claims. Applicant expressly reserves the right to argue the patentability of all claims

separately and to provide new, different, and/or additional arguments for patentability not set forth herein, including, but not limited to, the failure of cited references to disclose, teach, or suggest other elements of the claims, the lack of motivation to combine cited references, or teaching away from the combination of cited references, in this or any future proceedings.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date October 19, 2009

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